

1645

MAY 13 2002

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Attorney Docket No. 99-123-D)

In Re Application of:)	
)	
Yamamoto, et al.)	Examiner: Unassigned
)	
Serial No. 10/017,178)	Art Unit: 1645
)	
Filed: December 14, 2001)	
)	
For: High Throughput Assay to Detect)	
Inhibitors of the MAP Kinase Pathway)	

TRANSMITTAL LETTER

Commissioner for Patents
Washington, D.C. 20231

RECEIVED

MAY 15 2002

TECH CENTER 1600 2900

Dear Sir:

In regard to the above identified application,

1. We are transmitting herewith the attached:

- ☒ Information Disclosure Statement;
- ☒ Form PTO-1449 including (53 cited references); and
- ☒ Return Postcard

2. No fee is due at this time.

3. **GENERAL AUTHORIZATION TO CHARGE OR CREDIT FEES:** Please charge any additional fees or credit overpayment to Deposit Account No. 13-2490. A duplicate copy of this sheet is enclosed.

4. **CERTIFICATE OF MAILING UNDER 37 CFR § 1.8:** I hereby certify that I directed that this Transmittal Letter and the correspondence identified above be deposited with the United States Postal Service as "First Class Mail," addressed to the Commissioner for Patents, Washington, DC 20231 on May 9, 2002.

Respectfully submitted,



Andrew W. Williams
Registration No. 48,644



UNITED STATES PATENT AND TRADEMARK OFFICE
(Attorney Docket No. 99-123-D)

PATENT

In Re Application of:)
)
 Yamamoto, et al.) Examiner: Unassigned
)
 Serial No. 10/017,178) Art Unit: 1645
)
 Filed: December 14, 2001)
)
 For: High Throughput Assay to Detect)
 Inhibitors of the MAP Kinase Pathway)

RECEIVED

MAY 1 2002

TECH CE. 1 2002

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Pursuant to 37 C.F.R. §§1.97-1.98, and in accordance with the duty of candor set forth in 37 C.F.R. §1.56, Applicants wish to make the following references of record in the above-identified application. Copies of the references cited below are enclosed along with a copy of completed PTO Form-1449.

This application claims priority from U.S. Provisional Application No. 60/255,548 filed December 14, 2000, and is relied upon for an earlier filing date under 35 U.S.C. § 120.

CITED REFERENCES

I. U.S. PATENT DOCUMENTS

	<u>Document Number</u>	<u>Date</u>	<u>Name</u>
1.	3,791,932	2 12 1974	Schuurs et al.
2.	3,839,153	10 1 1974	Schurrs et al.
3.	4,342,566	8 3 1982	Theofilopoulos et al.
4.	4,493,795	1 15 1985	Nestor, Jr. et al.
5.	4,671,958	6 9 1987	Rodwell et al.

II. OTHER DOCUMENTS

7. Alessi et al., "PD098059 is a specific inhibitor of the activation of mitogen-activated protein kinase kinase in vitro and in vivo," *J. Biol. Chem.* 270:27489-27494 (1995).
8. Alwine, et al., "Method for detection of specific RNAs in agarose gels by transfer to diazobenzyloxymethyl-paper and hybridization with DNA probes," (1977), *Proc. Natl. Acad. Sci. USA*, 74:5350-5354.
9. Asada et al., "Increased expression of highly branched N-glycans at cell surface is correlated with the malignant phenotypes of mouse tumor cells," *Cancer Research* 57:1073-1080 (1997).
10. Avrameas et al., "Coupling of Enzymes to antibodies an antigens," *Scand. J. Immunol.*, Vol. 8, Suppl. 7:7-23 (1978).
11. Berchtold, "A simple method for direct cloning and sequencing cDNA by the use of a single specific oligonucleotide and oligo(dT) in a polymerase chain reaction (PCR)," (1989), *Nuc. Acids Res.*, 17(1):453.
12. Blood et al., "Tumor interactions with the vasculature: angiogenesis and tumor metastasis," *Biochem. Biophys. Acta* 1032:89-118 (1990).
13. Brooks et al., "Localization of matrix metalloproteinase MMP-2 to the surface of invasive cells by interaction with integrin $\alpha\beta_3$," *Cell* 85:683-693 (1996).
14. Clackson et al., "Making antibody fragments using phage display libraries," *Nature* 352:624-628 (1991).
15. Demetriou et al., "Reduced contact-inhibition and substratum adhesion in epithelial cells expressing GlcNac-transferase V," *J. Cell Biol.* 130:383-392 (1995).
16. Dennis et al., " β 1-6 branching of Asn-linked oligosaccharides is directly associated with metastasis," *Science* 236:582-585 (1987).
17. Der, et al., "Identification of genes differentially regulated by interferon α , β , or γ using oligonucleotide arrays," (1998), *Proc. Natl. Acad. Sci. USA*, Vol. 95, pp. 15623-15628.
18. Dulbecco et al., "Plaque Production by the Polyoma Virus," *Virol.*, 8:396-7 (1959).
19. Fernandes et al., " β 1-6 branched oligosaccharides as a marker of tumor progression in human breast and colon neoplasia," *Cancer Res.* 51:718-723 (1991).

20. Gladson et al., "Up-regulation of urokinase and urokinase receptor genes in malignant astrocytoma," *Am. J. Pathol.* 146:1150-1160 (1995).
21. Hakomori S., "Tumor malignancy defined by aberrant glycosylation and sphingo(glyco)lipid metabolism," *Cancer Res.* 56:5309-5318 (1996).
22. Harkin, et al., "Induction of GADD45 and JNK SAPK-Dependent Apoptosis following Inducible Expression of BRCA1," (1999), *Cell*, Vol. 97, pp. 575-586.
23. Hoogenboom et al., "Multi-subunit proteins on the surface of filamentous phage: methodologies for displaying antibody (Fab) heavy and light chains," *NAR* 19:4133-4137 (1991).
24. Huse et al., "Generation of a Large Combinatorial Library of the Immunoglobulin Repertoire in Phage Lambda," *Science* 246:1275-1281 (1989).
25. Kang et al., "Transcriptional regulation of the N-acetylglucosaminyl-transferase V gene in human bile duct carcinoma cells (HuCC-T1) is mediated by Ets-1," *J. Biol. Chem.* 271:26706-26712 (1996).
26. Kishima et al., "Monoclonal antibody ONS-M21 recognizes integrin alpha3 in gliomas and medulloblastomas," *Br. J. Cancer* 79:333-339 (1999).
27. Klipstein et al., "Vaccine for Enterotoxigenic Escherichia coli Based on Synthetic Heat-Stable Toxin Crossed-Linked to the B Subunit of Heat-Labile Toxin," *J. Infect. Dis.* 147:318-326 (1983).
28. Ko et al., "Regulation of the GnT-V promoter by transcription factor Ets-1 in various cancer cell lines," *J. Biol. Chem.* 274:22941-22948 (1999).
29. Kohler and Milstein, "Continuous cultures of fused cells secreting antibody of predefined specificity," *Nature*, 256:495-497 (1975).
30. Marks et al., "By-Passing Immunization: Building High Affinity Human Antibodies by Chain Shuffling," *Bio Technology* 10:779-785 (1992).
31. Matrisian et al., "Stromelysin transin and tumor progression," *Semin. Cancer Biol.* 1:121-125 (1990).
32. McCafferty et al., "Phage antibodies: filamentous phage displaying antibody variable domains," *Nature* 348:552-554 (1990).
33. Melton, et al., "Efficient in vitro synthesis of biologically active RNA and RNA hybridization probes from plasmids containing a bacteriophage SP6 promoter," (1984), *Nuc. Acids Res.*, 12:7035-7056.

34. Meuillet et al., "Sialidase gene transfection enhances epidermal growth factor receptor activity in an epidermoid carcinoma cell line, A431," *Cancer Res.* 59:234-240 (1999).
35. Nerlov et al., "Essential AP-1 and PEA3 binding elements in the human urokinase enhancer display cell-type specific activity," *Oncogene* 6:1583-1592 (1991).
36. Niman et al., "Generation of protein-reactive antibodies by short peptides is an event of high frequency: Implications for the structural basis of immune recognition," *PNAS USA*, 80:4949-4953 (1983).
37. Paulus et al., "Basement membrane invasion of glioma cells mediated by integrin receptors," *J. Neurosurgery* 80:515-519 (1994).
38. Paulus et al., "Characterization of integrin receptors in normal and neoplastic human brain," *Am. J. Pathol.* 143:154-161 (1993).
39. Rebbaa et al., "Gene transfection-mediated overexpression of β 1,4GlcNAc bisecting oligosaccharides in glioma cell lines, U373MG inhibits EGF receptor function," *J. Biol. Chem.* 272:9275-9279 (1997).
40. Robinson et al., "ETS target genes: Identification of Egr1 as a target by RNA differential display and whole genome PCR techniques," *Proc. Natl. Acad. Sci. USA* 94:7170-7175 (1997).
41. Rodwell et al., "Linker Technology: Antibody-Mediated Delivery Systems," *Biotech.* 3:889-894 (1985).
42. Sastry et al., "Cloning of the immunological repertoire in *Escherichia coli* for generation of monoclonal catalytic antibodies: Construction of a heavy chain variable region-specific cDNA library," *PNAS USA* 86:5728-5732 (1989).
43. Staudt et al., "Generation Of Antibody Diversity In The Immune Response Of BALB/c Mice To Influenza Virus Hemagglutinin," *J. Exp. Med.*, 157:687-704 (1983).
44. Uhm et al., "Mechanisms of glioma invasion: Role of matrix-metallproteinases," *Can. J. Neurol. Sci.* 24:1-15 (1997).
45. van Straaten et al., "Complete nucleotide sequence of a human c-onc gene: deduced amino acid sequence of the human c-fos protein," *Proc. Natl. Acad. Sci. USA* 80:3183-3187 (1983).
46. Wasylyk et al., "Reversion of Ras transformed cells by Ets transdominant mutants," *Oncogene* 9:3665-3672 (1994).

47. Wasylyk et al., "The c-ets proto-oncogenes encode transcriptional factors that cooperate with c-fos and c-jun for transcriptional activation," *Nature (London)* 346:191-193 (1990).
48. Wei et al., "Regulation of integrin function by the urokinase receptor," *Science* 273:1551-1555 (1996).
49. Wernert et al., "Stromal expression of c-Ets1 transcriptional factor correlates with tumor invasion," *Cancer Res.* 54:5683-5688 (1994).
50. Yamamoto et al., "Differential expression of membrane-type matrix metalloproteinase and its correlation with gelatinase A activation in human malignant brain tumors in vivo and in vitro," *Cancer Res.* 56:384-392 (1996).
51. Yamamoto et al., " α 2,6 sialyltransferase gene transfection into a human glioma cell line (U-373 MG) results in decreased invasivity," *J. Neurochem.* 68:2566-2576 (1997).
52. Yamamoto et al., " α 2,6-Sialylation of cell-surface N-glycans inhibits glioma formation in vivo," *Cancer Res.* 61:6822-6829 (2001).
53. Yamamoto et al., " β 1,6-GlcNAc-bearing N-glycans in human gliomas: Implications for a role in regulating invasivity," *Cancer Res.* 60:134-142 (2000).

III. DISCUSSION

Applicants submit that these documents, whether taken alone or in combination, fail to show or suggest the claimed subject matter. Applicants request that the Examiner consider the entirety of each document and make them of record in this application by initialing on Form PTO-1449. Such initialing is requested even if the Examiner does not consider a cited document to be sufficiently pertinent to use in a rejection, or otherwise does not consider it to be prior art for any reason, or even if the Examiner does not believe that Applicants have fully complied with the guidelines for citation. This is requested so that each document becomes listed on the face of the patent issuing on the present application. Applicants' submission of these documents for consideration is not to be construed as an admission that the documents qualify as prior art to the claimed subject matter, a

representation that a search has been made, nor as an admission that the information is considered to be material to patentability.

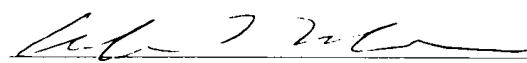
Portions of the references may be material to the examination of the pending claims, although no such admission is intended. 37 C.F.R. §1.97 (h). The references have not been reviewed in sufficient detail to make any other representation and, in particular, no representation is intended as to the relative importance of any portion of the references.

Respectfully Submitted,

McDonnell Boehnen Hulbert & Berghoff

Date: May 9, 2002

By:



Andrew W. Williams

Reg. No. 48,644

FORM PTO-1449
(Rev. 2-32)U.S. Department of Commerce
Patent and Trademark Office

Atty. Docket No.

Serial No.

99,123-D

10/017,178

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(Use several sheets if necessary)

Applicant:

Yamamoto, et al.

Filing Date:

12/14/2001

Group:

1645

RECEIVED

MAY 15 2002

TECH CENTER 1600 2900

U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	1.	3,791,932	2/12/1974	Schuurs et al.			
	2.	3,839,153	10/1/1974	Schurrs et al.			
	3.	4,342,566	8/3/1982	Theofilopoulos et al.			
	4.	4,493,795	1/15/1985	Nestor, Jr. et al.			
	5.	4,671,958	6/9/1987	Rodwell et al.			
	6.	4,900,811	2/13/1990	Sutcliffe			

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc).

7.	Alessi et al., "PD098059 is a specific inhibitor of the activation of mitogen-activated protein kinase kinase in vitro and in vivo," J. Biol. Chem. 270:27489-27494 (1995).
8.	Alwine, et al., "Method for detection of specific RNAs in agarose gels by transfer to diazobenzylloxymethyl-paper and hybridization with DNA probes," (1977), Proc. Natl. Acad. Sci. USA, 74:5350-5354.
9.	Asada et al., "Increased expression of highly branched N-glycans at cell surface is correlated with the malignant phenotypes of mouse tumor cells," Cancer Research 57:1073-1080 (1997).
10.	Avrameas et al., "Coupling of Enzymes to antibodies an antigens," Scand. J. Immunol., Vol. 8, Suppl. 7:7-23 (1978).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication.

MAY 15 1964

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.).

11.	Berchtold, "A simple method for direct cloning and sequencing cDNA by the use of a single specific oligonucleotide and oligo(dT) in a polymerase chain reaction (PCR)," (1989), <i>Nuc. Acids Res.</i> , 17(1):453.
12.	Blood et al., "Tumor interactions with the vasculature: angiogenesis and tumor metastasis," <i>Biochem. Biophys. Acta</i> 1032:89-118 (1990).
13.	Brooks et al., "Localization of matrix metalloproteinase MMP-2 to the surface of invasive cells by interaction with integrin $\alpha v \beta 3$," <i>Cell</i> 85:683-693 (1996).
14.	Clackson et al., "Making antibody fragments using phage display libraries," <i>Nature</i> 352:624-628 (1991).
15.	Demetriou et al., "Reduced contact-inhibition and substratum adhesion in epithelial cells expressing GlcNac-transferase V," <i>J. Cell Biol.</i> 130:383-392 (1995).
16.	Dennis et al., " $\beta 1$ -6 branching of Asn-linked oligosaccharides is directly associated with metastasis," <i>Science</i> 236:582-585 (1987).
17.	Der, et al., "Identification of genes differentially regulated by interferon α , β , or γ using oligonucleotide arrays," (1998), <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 95, pp. 15623-15628.
18.	Dulbecco et al., "Plaque Production by the Polyoma Virus," <i>Virology</i> , 8:396-7 (1959).
19.	Fernandes et al., " $\beta 1$ -6 branched oligosaccharides as a marker of tumor progression in human breast and colon neoplasia," <i>Cancer Res.</i> 51:718-723 (1991).
20.	Gladson et al., "Up-regulation of urokinase and urokinase receptor genes in malignant astrocytoma," <i>Am. J. Pathol.</i> 146:1150-1160 (1995).
21.	Hakomori S., "Tumor malignancy defined by aberrant glycosylation and sphingo(glyco)lipid metabolism," <i>Cancer Res.</i> 56:5309-5318 (1996).
22.	Harkin, et al., "Induction of GADD45 and JNK/SAPK-Dependent Apoptosis following Inducible Expression of BRCA1," (1999), <i>Cell</i> , Vol. 97, pp. 575-586.
23.	Hoogenboom et al., "Multi-subunit proteins on the surface of filamentous phage: methodologies for displaying antibody (Fab) heavy and light chains," <i>NAR</i> 19:4133-4137 (1991).
24.	Huse et al., "Generation of a Large Combinatorial Library of the Immunoglobulin Repertoire in Phage Lambda," <i>Science</i> 246:1275-1281 (1989).
25.	Kang et al., "Transcriptional regulation of the N-acetylglucosaminyl-transferase V gene in human bile duct carcinoma cells (HuCC-T1) is mediated by Ets-1," <i>J. Biol. Chem.</i> 271:26706-26712 (1996).
26.	Kishima et al., "Monoclonal antibody ONS-M21 recognizes integrin $\alpha 3$ in gliomas and medulloblastomas," <i>Br. J. Cancer</i> 79:333-339 (1999).
27.	Klipstein et al., "Vaccine for Enterotoxigenic Escherichia coli Based on Synthetic Heat-Stable Toxin Crossed-Linked to the B Subunit of Heat-Labile Toxin," <i>J. Infect. Dis.</i> , 147:318-326 (1983).
28.	Ko et al., "Regulation of the GnT-V promoter by transcription factor Ets-1 in various cancer cell lines," <i>J. Biol. Chem.</i> 274:22941-22948 (1999).
29.	Kohler and Milstein, "Continuous cultures of fused cells secreting antibody of predefined specificity," <i>Nature</i> , 256:495-497 (1975).
30.	Marks et al., "By-Passing Immunization: Building High Affinity Human Antibodies by Chain Shuffling," <i>Bio/Technology</i> 10:779-785 (1992).
31.	Matrisian et al., "Stromelysin/transin and tumor progression," <i>Semin. Cancer Biol.</i> 1:121-125 (1990).

EXAMINER	DATE CONSIDERED
----------	-----------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication.

RECEIVED

MAY 15 2000

Sheet 3 of 4

MAY 15 2000

OTHER DOCUMENTS (Including Author, Title, Date, Page, etc.)

32.	McCaferly et al., "Phage antibodies: filamentous phage displaying antibody variable domains," Nature 348:552-554 (1990).
33.	Melton, et al., "Efficient in vitro synthesis of biologically active RNA and RNA hybridization probes from plasmids containing a bacteriophage SP6 promoter," (1984), Nuc. Acids Res., 12:7035-7056.
34.	Meuillet et al., "Sialidase gene transfection enhances epidermal growth factor receptor activity in an epidermoid carcinoma cell line, A431," Cancer Res. 59:234-240 (1999).
35.	Nerlov et al., "Essential AP-1 and PEA3 binding elements in the human urokinase enhancer display cell-type specific activity," Oncogene 6:1583-1592 (1991).
36.	Niman et al., "Generation of protein-reactive antibodies by short peptides is an event of high frequency: Implications for the structural basis of immune recognition," PNAS USA, 80:4949-4953 (1983).
37.	Paulus et al., "Basement membrane invasion of glioma cells mediated by integrin receptors," J. Neurosurgery 80:515-519 (1994).
38.	Paulus et al., "Characterization of integrin receptors in normal and neoplastic human brain," Am. J. Pathol. 143:154-161 (1993).
39.	Rebbaa et al., "Gene transfection-mediated overexpression of β 1,4GlcNAc bisecting oligosaccharides in glioma cell lines, U373MG inhibits EGF receptor function," J. Biol. Chem. 272:9275-9279 (1997).
40.	Robinson et al., "ETS target genes: Identification of Egr1 as a target by RNA differential display and whole genome PCR techniques," Proc. Natl. Acad. Sci. USA 94:7170-7175 (1997).
41.	Rodwell et al., "Linker Technology: Antibody-Mediated Delivery Systems," Biotech. 3:889-894 (1985).
42.	Sastry et al., "Cloning of the immunological repertoire in Escherichia coli for generation of monoclonal catalytic antibodies: Construction of a heavy chain variable region-specific cDNA library," PNAS USA 86:5728-5732 (1989).
43.	Staudt et al., "Generation Of Antibody Diversity In The Immune Response Of BALB/c Mice To Influenza Virus Hemagglutinin," J. Exp. Med., 157:687-704 (1983).
44.	Uhm et al., "Mechanisms of glioma invasion: Role of matrix-metalloproteinases, Can. J. Neurol. Sci. 24:1-15 (1997).
45.	van Straaten et al., "Complete nucleotide sequence of a human c-onc gene: deduced amino acid sequence of the human c-fos protein," Proc. Natl. Acad. Sci. USA 80:3183-3187 (1983).
46.	Wasylyk et al., "Reversion of Ras transformed cells by Ets transdominant mutants," Oncogene 9:3665-3672 (1994).
47.	Wasylyk et al., "The c-ets proto-oncogenes encode transcriptional factors that cooperate with c-fos and c-jun for transcriptional activation," Nature (London) 346:191-193 (1990).
48.	Wei et al., "Regulation of integrin function by the urokinase receptor," Science 273:1551-1555 (1996).
49.	Wernert et al., "Stromal expression of c-Ets1 transcriptional factor correlates with tumor invasion," Cancer Res. 54:5683-5688 (1994).
50.	Yamamoto et al., "Differential expression of membrane-type matrix metalloproteinase and its correlation with gelatinase A activation in human malignant brain tumors in vivo and in vitro," Cancer Res. 56:384-392 (1996).
51.	Yamamoto et al., "alpha2,6 sialyltransferase gene transfection into a human glioma cell line (U-373 MG) results in decreased invasivity," J. Neurochem. 68:2566-2576 (1997).
52.	Yamamoto et al., "alpha2,6-Sialylation of cell-surface N-glycans inhibits glioma formation in vivo," Cancer Res. 61:6822-6829 (2001).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication.

OTHER DOCUMENTS
MAY 15 2002

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc).

	53.	Yamamoto et al., "β1,6-GlcNAc-bearing N-glycans in human gliomas: Implications for a role in regulating invasivity," Cancer Res. 60:134-142 (2000).
--	-----	---

RECEIVED

MAY 15 2002

TECH CENTER 1600 2002

EXAMINER	DATE CONSIDERED
----------	-----------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication.